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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,954	03/27/2001	Christopher J.R. Paszty	A-676B	9125

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EXAMINER

SPECTOR, LORRAINE

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/818,954

**Applicant(s)**

PASZTY ET AL.

**Examiner**

Lorraine Spector, Ph.D.

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8,10,11,47-51,61 and 65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,10,11,47-51,61 and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Applicants petition having been granted, prosecution is reopened. Claims 1-8, 10, 11, 47-51, 61 and 65 are pending and under consideration. New provisional double patenting rejections are applied.

***Claim Objections***

Claim 8 remains objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can depend from multiple other claims in the alternative only. Claim 8 depends from claims 1, 2 or 3, *and* claim 5. See MPEP § 608.01(n). Correction is required.

The Examiner regrets the typographical error in the previous Office Action. Nonetheless, applicants have taken no action to remedy the problem.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10, 11, 47-51, 61 and 65 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims that recite specific stringent conditions, such as claims 1-3, remain indefinite because the metes and bounds of what will be obtained via such hybridization are at least as dependent upon the wash conditions (time and buffers) as they are upon the actual hybridization conditions. It is noted that applicants have now amended the claims to recite that hybridization is followed by "at least one wash step." However this does not substantively change the claims, as the person of ordinary skill in the art would have known that such a wash step was inherent to the process, and because no *specific* wash conditions are stated, as required above.

Claim 3 as amended is indefinite at part (b), which states that the claimed nucleic acid encodes "a mature form", but allows insertions at the amino terminus of the polypeptide. Accordingly, the metes and bounds of the claim cannot be determined. Further, part (e) of the

claim states that the encoded protein is “a mature” form but allows N- and C- terminal deletions, which conflicts with the art-accepted meaning of “mature” form of a protein.

Claim 10 as amended is indefinite because it is not clear whether applicants intend that the “native” promoter DNA is absent or not.

Claim 65 as amended is indefinite for lacking sufficient method steps or elements. There is nothing recited in the claim or claim 5, from which it now depends, that would allow production of an  $\alpha 2$  subunit.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10, 11, 47-51, 61 and 65 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO: 2 or that encodes SEQ ID NO: 1, does not reasonably provide enablement for the breadth of the claims, which encompass numerous fragments, derivatives, etc. of such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Although portions of the claims have been amended to limit to 90% rather than the previously recited 75% identity, the issues remain the same; using claim 2 as an example, it is only part (a) of the claim that is so limited. Even if the limitation were absolute, the rejection would be maintained. While  $\alpha 2/\beta 10$  heterodimer binds to TSH receptors, it remains that that no activity has been shown to result from that; there is no evidence of record that the claimed subunit “is capable of regulating thyroidal function or promoting thyroid differentiation or proliferation”. The newly discovered subunit may or may not stimulate the TSH receptor. It might just as well *prevent* signaling through that receptor. In the absence of any information as to what the biological activity is, the specification merely provides an invitation to experiment to determine what the  $\alpha 2/\beta 10$  heterodimer does, and then develop methods of using it based upon

those observations. Such an invitation to experiment is not enabling. As stated previously, the only *enabled* use for the  $\alpha 2/\beta 1$  heterodimer is for thyroid imaging. With respect to the breadth of the claims, while claim 2 has been narrowed, claims that recite hybridization conditions have not. Nonetheless, *none* of the claims are enabled in scope. The specification provides no guidance or working examples of variants of the disclosed  $\beta 10$  subunit, and given the previously considered evidence that the effect of structural alterations in the glycoprotein hormones is not predictable (Nakabayashi et al.), and that the newly identified glycoprotein hormone differs substantively from the previously known four species, in that its subunits may *not* be interchanged with those of the other known family members. Thus, the art evidences a lack of predictability in making alterations to glycoprotein hormones in general, and  $\alpha 2/\beta 10$  in particular. Accordingly, the rejection is maintained.

Claims 1-8, 10, 11, 47-51, 61 and 65 remain rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in the first office action on the merits, mailed 11/21/2002.

Applicants arguments, filed 11/10/2005, have been fully considered but are not deemed persuasive for reasons of record.

#### ***Claim Rejections - 35 USC § 102 and 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4-5, 7 and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative under 35 U.S.C. § 103(a) as being obvious over G.G. Mahairas et al., Locus AQ495547 disclosed 4/28/99 for reasons of record. Applicants argument that the previous Office Action did not provide support for finding the argument non-persuasive is not accurate. Quoting the previous Office Action, "Applicants traversal that the reference does not teach a nucleic acid that would encode a protein with the newly recited activity has been fully considered but is not deemed persuasive; *see part (d) of claim 2.*" (Emphasis added.) Also as previously stated, Mahairas teaches a sequence 100% identical to bases 22-209 of SEQ ID NO: 2.

Applicants arguments have been fully considered but are not deemed persuasive. Applicants argue that the reference "must singly identify each and every feature recited in the claim". This argument has been fully considered but is not deemed persuasive because the reference must teach only a *single* claimed embodiment, not the entire breadth of the claim. With respect to the functional limitation, such is deemed, in the absence of fact or evidence to the contrary, to be inherent to the prior art sequence; see the Office Action mailed 11/21/2002, first full paragraph of page 11. Contrary to applicants argumenet that the reference must teach both how to make and how to use the claimed invention, all that is required for anticipation is that the reference teach how to *make* what is claimed, in a manner that would enable said

making. In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. *In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992) (The application claimed compounds used in ophthalmic compositions to treat dry eye syndrome. The examiner found a printed publication which disclosed the claimed compound but did not disclose a use for the compound. The court found that the claim was anticipated since the compound and a process of making it was taught by the reference. The court explained that “no utility need be disclosed for a reference to be anticipatory of a claim to an old compound.” 964 F.2d at 1124, 22 USPQ2d at 1673. It is enough that the claimed compound is taught by the reference.). See MPEP 2122.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10, 11, 47-51, 61 and 65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10, 11, 47-51, 61 and 65 of copending Application No. 10/449140. Although the conflicting claims are

not identical, they are not patentably distinct from each other because they overlap extensively in scope; the copending claims correspond to the instant claims as originally filed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed



copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to 571-273-8300. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Lorraine Spector". The signature is fluid and cursive, with a large initial "L" and a long, sweeping underline.

Lorraine Spector, Ph.D.  
Primary Examiner

6/15/2006